

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

MAY 2 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

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MEMORANDUM

SUBJECT:

PP #4G3156. HOE-39866 on soybeans, non-crop areas and non-bearing tree and vine crops. Comments on the amendment of March 7, 1985. Accession Nos. 073420.

RCB #831 and #832.

TROM:

John M. Worthington, Chemist

Residue Chemistry Branch

Hazard Evaluation Division (TS-769)

TO:

Richard Mountford, PM. No. 23
Registration Division (TS-767)

and

Toxicology Branch

Hazard Evaluation Division (TS-769)

THRU:

Charles L. Trichilo, Chief

Residue Chemistry Branch

Hazard Evaluation Division (TS-769)

American Hoechst Corporation proposed in PP #4G3156 the establishment of temporary tolerances for residues of the herbicide, monoammonium 2-amino-4-(hydroxymethylphosphinyl) butanoate, trade name HOE-39866, and its metabolite, 3-methylphosphinicopropoinic acid, in or on soybeans at 0.02 ppm.

The petitioner was informed by Registration Division in the letter of 1/14/85 of the following requirements for a favorable recommendation (See also our memo of 1/2/85 by J. Worthington):

- a) Either revalidation of the proposed procedures demonstrating that the fortified blank control is not necessary, or modification of the proposed methods to eliminate the need for the fortified blank control standard.
- b) Proposal of 0.02 ppm tolerances residues in grapes and citrus, pome and stone fruits.
- c) Imposition of a label restriction against the feeding or grazing of treated soybean forage.
- d) Imposition of a label restriction against the feeding or grazing of treated orchard cover crops.

In response to Requirement #1, the petitioner has submitted additional validation data reflecting the modified procedure which does not employ the use of fortified blank control standard. Recovery values from soybeans fortified at levels ranging from 0.05 to 0.1 ppm averaged 83.2% but ranged from 46.6% to 128%. The same samples analyzed using the fortified blank control technique showed somewhat higher and more consistent values. The control values ranged from 0.008 to 0.010 ppm. These data indicate that the proposed method is sensitive to 0.05 ppm HOE-39866 in soybeans (rather than the 0.02 ppm originally reported).

The additional data taken in conjunction with the previously submitted recovery data demonstrate that the proposed procedure is suitable for the enforcement of a 0.05 ppm temporary tolerance. However, due to the variability of the recoveries, the proposed procedure is not adequate for the enforcement of a future permanent tolerance.

For a future permanent tolerance, modification of the proposed procedure to produce more consistent recovery of HOE-39866 from treated commodities will be required. Further, additional validation data, including chromatograms, for the analysis of HOE-39866 and its principal metabolite by the modified procedure will be required. The validation data must include representative crops from all the crop groups for which tolerances are proposed.

In response to Requirement #2, the petitioner, as requested, has proposed a 0.02 ppm tolerance for residue of HOE-39866 in grapes, citrus, pome and stone fruits. However, considering the fact that the proposed method has only been shown to be sensitive to 0.05 ppm, proposal of 0.05 ppm temporary tolerance for residues of HOE-39866 in soybeans, grapes, citrus, pome and stone fruits is needed.

In response to Requirements #2 and #3, the petitioner has included the required restrictions on the proposed label.

Recommendations

- 1. Contingent upon the proposal of a 0.05 ppm tolerance level Residue Chemistry Branch recommends that the proposed temporary tolerance for residues of monoammonium 2-amino-4-(hydroxymethylphosphinyl) butanoate and its metabolite, 3-methylphosphinicopropoinic acid, in or on soybeans, grapes, citrus, stone and pome fruits be established.
- 2. For a future permanent tolerance the following will be required:
 - a) A list of the identity of the individual impurities and their percentages of the technical material.

- b) An appropriate ruminant metabolism study.
- c) Storage stability data demonstrating that residues are stable under the conditions of storage.
- d) Modification of the proposed analytical method to produce more consistent recovery of HOE-39866 from treated commodities.
- e) Additional validation data, including chromatograms, for the analysis of HOE-39866 and its principal metabolite by the modified procedure. The validation data must include representative crops from all the crop groups for which tolerances are proposed.
- f) Additional residue data developed using the revised analytical procedure and reflecting the residue levels resulting in treated crops from the proposed use.
- g) Depending on the results of the ruminant metabolism study, appropriate animal feeding studies and possibly tolerance proposals for residues in milk, meat, poultry and eggs may be required.

cc: PP# 4G3156
PM-25
TOX
J. Worthington
Reading file
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FDA
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TS-769:Reviewer:JMWORTHINGTON:Date:4/22/85 RDI:Section Head:ARR:Date:5/2/85:RDS:Date:5/2/85 Edit by LDJ:5/2/85